

(NaOH page 1036 and HCl page 1034) or the Official Methods of Analysis of the Association of Official Analytical Chemists, 11th Ed., 1970, (NaOH page 876 and HCl page 873), which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, 2200 Wilson Blvd., suite 400, Arlington, VA 22201-3301, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

[39 FR 19874, June 4, 1974; 39 FR 22140, June 20, 1974, as amended at 47 FR 9396, Mar. 5, 1982; 55 FR 11581, Mar. 29, 1990]

EFFECTIVE DATE NOTE: At 61 FR 4823, Feb. 8, 1996, § 331.23 was removed, effective February 10, 1997.

§ 331.23 Temperature standardization.

All tests shall be conducted at 25° C±3°, or 37° C±3°.

[40 FR 48343, Oct. 15, 1975]

EFFECTIVE DATE NOTE: At 61 FR 4823, Feb. 8, 1996, § 331.23 was removed, effective February 10, 1997.

§ 331.24 Tablet disintegration test.

A tablet disintegration test shall be performed on tablets that are not to be chewed following the procedures described in the United States Pharmacopeia XVIII (page 932). If the label states the tablet may be swallowed, it must disintegrate within a 10-minute time limit pursuant to the test procedure using simulated gastric fluid test solution without enzymes, the United States Pharmacopeia XVIII page 1026, rather than water as the immersion fluid.

EFFECTIVE DATE NOTE: At 61 FR 4823, Feb. 8, 1996, § 331.24 was removed, effective February 10, 1997.

§ 331.25 Preliminary antacid test.

(a) *pH meter.* Standardize the pH meter at pH 4.0 with the standardizing buffer and check for proper operation at pH 1 with 0.1 N HCl.

(b) *Dosage form testing—(1) Liquid sample.* Place an accurately weighed (calculate density) and well mixed amount of the antacid product equivalent to the minimum labeled dosage; e.g., 5 ml., into a 100 ml. beaker. Add sufficient water to obtain a total volume of about 40 ml. and mix on magnetic stir-

rer at 300±30 r.p.m. for about one minute. Analyze the sample according to the procedure set forth in § 331.25.

(2) *Chewable and non-chewable tablet sample.* Place an accurately weighed amount of a tablet composite equivalent to the minimum labeled dosage into a 100 ml. beaker. (The composite shall be prepared by determining the average weight of not less than 20 tablets and then comminuting the tablets sufficiently to pass through a number 20 U.S. standard mesh sieve and held by a number 100 U.S. standard mesh sieve.) Mix the sieved material to obtain a uniform sample. If wetting is desired, add not more than 5 ml. of 95 percent ethanol and mix to wet the sample thoroughly (ethanol may effect the acid neutralizing capacity). Add water to a volume of 40 ml. and mix on magnetic stirrer at 300±30 r.p.m. for about one minute. (Capsules should be tested in the same manner using the sieved capsule powder as the sample.) Analyze the sample according to the procedure set forth in § 331.25.

(3) *Effervescent sample.* Place an amount equivalent to the minimum labeled dosage into a 100 ml. beaker. Add 10 ml. water and swirl the beaker gently while allowing the reaction to subside. Add another 10 ml. of water and swirl the beaker gently. Wash down the walls of the beaker with 20 ml. of water and mix on magnetic stirrer at 300±30 r.p.m. for about one minute. Analyze the sample according to the procedure set forth in § 331.25.

(4) *Chewing gum samples with antacid in coating.* Place the number of pieces of gum equivalent to the minimum labeled dosage in a 100 ml. beaker. Add 40 ml. of water and mix on magnetic stirrer at 300±30 r.p.m. for about 2 to 3 minutes. Analyze the sample according to the procedure set forth in § 331.25.

(c) *Test procedure.* (1) Add 10.0 ml. 0.5 N HCl to the test solution while stirring on the magnetic stirrer at 300±30 r.p.m.

(2) Stir for exactly 10 minutes after addition of acid.

(3) Read and record pH.

(4) If pH is below 3.5, the product shall not be labeled as an antacid. If the pH is 3.5 or greater, determine the acid neutralizing capacity according to the procedure set forth in § 331.26.